5 Overview of the Pesticide Risk Assessment and the Regulatory Process

C. Lee-Steere and T. Steeger

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5.1 INTRODUCTION

As discussed earlier, regulatory authorities have the responsibility to evaluate pesticides and the potential risks associated with their use. They have developed tools and methods to do this in a consistent manner with respect to different taxons. However, with the introduction of new plant protection products, changes in agricultural practices, and advances in the understanding of honey bee health and ecology, the ability to accurately characterize potential risks to insect pollinators with the existing tool set has been seen as a challenge. While many countries share the same broad risk-based environmental assessment approach, differences between approaches exist that account for national conditions, such as policies, legal requirements, or preferences.

The Workshop considered a generic, tiered risk assessment methodology, and worked to develop a process that included three phases: (1) problem formulation, (2) exposure, and (3) effects assessment, risk characterization. In Phase 1 (i.e., problem formulation), measurement endpoints, derived from studies, are selected with an understanding of how they relate to assessment endpoints (and ultimately specific protection goals and generic protection goals); a conceptual model is prepared that describes a risk hypothesis; and an analysis plan to test that hypothesis is described. In Phase 2 (i.e., analysis), measures of exposure and effects are evaluated. In Phase 3 (i.e., risk characterization), measures of exposure and measures of effect are integrated to develop risk estimates, and uncertainties are discussed.

Analysis is carried out in a tiered manner, where a Tier 1 analysis is intended to be a conservative screen that efficiently separates compounds that are not anticipated to present a potential risk from those compounds that may. Higher tiers are intended to refine the estimates or measures of potential exposure, effects, and the resulting characterization of risk. Risk assessors and risk managers proceed through the risk assessment process (i.e., ascending through higher tiers of analysis) to determine whether the intended use of a compound is consistent with defined protection goals. If the estimate of risk indicates that proposed use is not consistent

Pesticide Risk Assessment for Pollinators, First Edition. Edited by David Fischer and Thomas Moriarty.

with the protection goals, then risk mitigation techniques may be implemented proactively to resolve concerns. During the Workshop, risk mitigation was briefly discussed as it is a component of the overall regulatory management of plant protection products (see Chapter 13).

5.2 CURRENT APPROACH FOR ASSESSING EFFECTS OF PESTICIDE PRODUCTS TO POLLINATORS

In the United States, the first tier of toxicity testing with honey bees consists of an acute contact toxicity test (USEPA, 2012a) with adult honey bees that provides a median Lethal Dose (LD50), that is, the dose that causes death to 50% of the exposed organisms from a single dose of the test compound, along with any sublethal effects that may have occurred as a result of chemical exposure. The acute LD50 is assessed after 24 and 48 hours, but depending upon the outcome of the test, its duration can be extended up to a maximum of 96 hours, if necessary. Based upon the outcome of the acute LD50 toxicity test, pesticides are classified as practically non-toxic, moderately toxic, or highly toxic to bees on an acute exposure basis. If the LD50 is less than 11 μg/bee, additional testing may be required in the form of a foliar residue study (USEPA, 2012b) to determine the duration over which field-weathered foliar residues remain toxic to honey bees. On a case-by-case basis, additional higher-tiered studies such as field pollinator studies with honey bees (USEPA, 2012c) (i.e., hive studies) may be necessary if the data from toxicity studies indicate potential chronic effects or adverse effects on colonies.

In the European Union (EU), risk to honey bees from exposure to pesticides is based on the European and Mediterranean Plant Protection Organization (EPPO) process and includes a three-tiered progression of testing (2010)[1]. Guidelines describe laboratory tests, (OECD, 1998a, 1998b), as well as semi-field (cage/tunnel) tests, and field tests for evaluating the lethal and sub-lethal effects of pesticides on adult honey bees (OECD, 2007; EPPO, 2010). The testing approach in the EU is similar to that of the United States and Canada in that it consists of a tiered approach, where laboratory studies are considered Tier 1 tests, and semi-field and field tests are considered higher tiers. In contrast to the United States, the EU and Canada require the acute oral toxicity (LD50) on adult workers (OECD, 1998a) in addition to the acute contact toxicity (OECD, 1998b). In the EU, it is also standard practice to conduct both acute oral and acute contact LD50 studies on formulated end-use products, in cases where either exposure to the end use product itself is possible, or in the case where products have more than one active component, as well as the technical grade (relatively pure) active substance.

In addition to guideline toxicity test requirements, regulatory authorities around the world also make use of published open literature and dedicated studies for nontarget arthropods to evaluate the potential effects of pesticides on terrestrial invertebrates, or as a line of evidence to require higher tiered testing. Along with guideline and open literature studies, adverse effect (e.g., bee kill incident) reports, and monitoring studies are considered in order to gauge the effects of pesticides on nontarget organisms.

5.2.1 Risk Assessment for Systemic Compounds

Many who are familiar with pesticide risk assessment recognize that the methodology and assessment schemes employed for foliar application products (where exposure may be primarily through surface contact) are not well adapted to assess potential risk from compounds with systemic properties. With better understanding of the ability of these chemicals to be present in pollen and nectar during flowering, there has followed a

[1] Risk Assessment: PP 3/10 (2) (OEPP/EPPO), Test Methodologies: Guideline No. 170 (OEPP/EPPO); OECD 75.

better understanding of how systemic compounds present potential for both oral and contact exposure and, therefore, need to be considered.

The EPPO has recently put forward a risk assessment scheme (Alix et al., 2009) for systemic compounds that includes the same tiered testing system, but replaces the hazard quotient (HQ) calculation with a toxicity exposure ratio (TER), where TER = PNEC/PEC. The PNEC is the Predicted No Effect Concentration, while the PEC is the Predicted Exposure Concentration. The PEC is determined from estimated or measured residue concentrations in the whole plant, flowers, pollen and/or nectar. The dose that individual bees might ingest is then calculated for different categories of honey bees (e.g., larvae, queen, foragers) depending on the amount of contaminated pollen and nectar they may consume. PNECs are derived from acute, sublethal, and chronic toxicity data and may also include a factor to account for uncertainty. These factors range from 1 to 10 depending on whether the toxicity endpoint is assessed in a laboratory (Tier 1) or in a semi-field or field test, that is, uncertainty decreases as toxicity data become more representative of how the pesticide will be used.

5.2.2 Trigger Criterion and Levels of Concern

A "trigger criterion" is a value, a threshold, used to define the limit of risk that is consistent with protection goals. A trigger criterion or level of concern (LOC) is compared to a quantitative risk estimate (e.g., HQ employed in Europe, or a risk quotient (RQ) employed in North America (USEPA, 1998)) to determine if the estimated risk is acceptable or not. If the comparison between an LOC and an estimated risk indicates that the use of a compound is inconsistent with defined protection goals, then it may be appropriate to either further refine the risk with additional data, or seek action to mitigate potential risk (In Europe, for example, when assessing a spray formula, the trigger criterion at the screening level is where HQ $\geq$50; such that when HQ $\geq$50, either higher tier data, or risk mitigation may be sought (Alix et al., 2009; EPPO, 2010.). In the United States, estimates of risk (i.e., RQ) are compared against the LOC to determine whether further refinement is needed. Participants of the Workshop noted that while levels of concern promote efficiency in decision making, risk assessment is an iterative process between risk assessors and risk managers, and is composed of multiple lines of evidence in order to determine whether the use of a compound on a specific crop is consistent with protection goals. Ultimately, trigger criterion and levels of concern are policy tools and, as such, they are outside the purview of the SETAC Pellston Workshop and remain the right and responsibility of respective regulatory authorities to define.

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